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| APPLICATION NO.                                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/620,710                                                          | 07/16/2003  | Andrew J. Ries       | P-11517.01          | 9593             |
| 27581                                                               | 7590        | 08/02/2006           | EXAMINER            |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARK<br>MINNEAPOLIS, MN 55432-9924 |             |                      | HELLER, TAMMIE K    |                  |
|                                                                     |             |                      | ART UNIT            | PAPER NUMBER     |

3766

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/620,710 | <b>Applicant(s)</b><br>RIES ET AL. |  |
|                              | <b>Examiner</b><br>Tammie Heller     | <b>Art Unit</b><br>3766            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-29 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed on June 2, 2006 has been received and considered. By this amendment, claims 1-29 are now pending in the application.

#### ***Drawings***

2. In view of Applicant's submission of corrected drawing sheets, the Examiner withdraws the objection which was made against the drawings in the previous Office Action.

#### ***Double Patenting***

3. The provisional rejection of claims (1, 7, 13, 16, and 19), (3, 9, and 13), (4, 10, and 13), (5 and 11), and (6, 12, 18, and 21) on the ground of obviousness-type double patenting as being unpatentable over claims (6, 13, and 14), 7, 8, 9, and 10, respectively, of copending Application No. 10/10/465,158 will be held in abeyance until such time as claims in the present or other applications are otherwise allowable.

#### ***Response to Arguments***

4. Applicant's arguments, see page 15, lines 4-12, filed June 2, 2006, with respect to the rejection(s) of claim(s) 1, 2, 4, 5, 7, 8, 10, 11, 16-20, 23, 25, and 28 under 35 U.S.C. 102(b) in view of Levine have been fully considered and are persuasive in part. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Scheiner.

5. Applicant's arguments filed June 2, 2006 have been fully considered but they are not persuasive.

6. Regarding the rejection of claims 1, 2, 4, 6-8, 10, 12, 16, and 19-24, under 35 U.S.C. 102(b) as being anticipated by Scheiner, the Applicant argues that Scheiner fails to disclose a lead that includes a connector contact. Further, Applicant argues that yoke 241 of Scheiner is not capable of acting as an auxiliary connector port. The Examiner respectfully disagrees with this assertion. Scheiner discloses in Figures 6-10 a cross section of lead body 242 attached to the leads 250 via yoke 241. As can be seen in the figures, conductor 246 extends from the leads 250 to the lead body 242 via a connection at yoke 241. Therefore, yoke 241 acts as an auxiliary port to connect the leads 250 to the lead body 242. Further, the conductors 246 act as connector contacts in the yoke in order to electrically couple the leads to the lead body 242.

7. Regarding the rejection of claims 1-4, 7-10, 16, 19, 20, and 23, under 35 U.S.C. 102(b) as being anticipated by Smyth, the Applicant argues that Smyth fails to disclose a lead that includes a connector contact. Further, Applicant argues that junction 30 is not capable of acting as an auxiliary connector port. The Examiner respectfully disagrees with this assertion. Coil 72 acts as a connector contact at junction 30 to mechanically couple leads 12 and 14 to the body of the lead 10. Therefore, junction 30 must inherently act as an auxiliary connector port to connect leads 12 and 14 to the lead 10, and therefore connect to the medical device.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims (1, 7, 13, 16, and 19), (3, 9, and 13), (4, 10, and 13), (5 and 11), and (6, 12, 18, and 21) are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims (6, 13, and 14), 7, 8, 9, and 10, respectively, of copending Application No. 10/465,158. Although the conflicting

claims are not identical, they are not patentably distinct from each other because the auxiliary port in the present application acts as an adaptor, as described in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 4, 6-8, 10, 12, 16, and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner et al. (U.S. Patent No. 6,212,434), herein Scheiner. Regarding claims 1, 7, 16, 19, 20, and 23, Scheiner discloses a single-pass lead system which includes a first lead 254 including a first electrode 260 and a second electrode 262 (see Figure 4). It is inherent that the device of Scheiner includes first and second insulated conductors for connecting the first and second electrodes, 260 and 262, of the first lead to the implantable medical device 440. Further, the Examiner takes the position that yoke 241 is capable of acting as an auxiliary connector port which includes first, second, and third, conductor elements for connecting to the electrodes of the first lead. The system of Scheiner further includes a second lead 250 including an electrode 258 for high-voltage therapy. It is inherent that the second lead includes an insulated conductor for connecting the electrode 258 with the implantable medical device 440. As

shown in Figure 4, the auxiliary port 241 engages the second lead and thereby couples the connector element of the second lead to the connector element of the first lead. Further, as shown in Figure 15a, the connector port of the IMD 440 is adapted to engage the connector terminal of the first lead.

12. Regarding claim 2 and 8, the system of Scheiner is inherently capable of applying high-voltage therapy.

13. Regarding claim 4 and 10, it is inherent within the system of Scheiner that the second conductor of the first lead couples the second electrode to the second connector element of the first lead.

14. Regarding claims 6, 12, 21, 22, and 24, Scheiner discloses in Figure 15A that the lead may include up to four electrodes, electrodes 453, 454, 461, and 462. Therefore, Scheiner discloses third and fourth electrodes which would inherently require fourth and fifth insulated conductors to couple the electrodes to the connector.

15. Claims 1-4, 7-10, 16, 19, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Smyth et al. (U.S. Patent No. 4,393,883), herein Smyth. Regarding claims 1, 7, 16, 19, 20, and 23, Smyth discloses a single pass lead which includes a first lead 12 including a first electrode 20, first insulated conductor 84 and second insulated conductor 72 (see Figures 1 and 2). Smyth further discloses that the system may employ bipolar electrodes (see col. 2, ln. 51-53), therefore it is disclosed that the first lead may include a second electrode. The Examiner takes the position that junction 30 acts as an auxiliary connector port which includes first, second, and third conductor

elements for connecting to the electrodes of the first lead. The invention of Smyth further includes a second lead 14 including electrode 16 for high-voltage therapy and insulated conductor 70 for connecting electrode 16 to the implantable medical device. As shown in Figure 2, the auxiliary port 30 engages the second lead and thereby couples the connector element of the second lead to the connector element of the first lead. Furthermore, in Figure 1, Smyth illustrates that connector pin 28 of the first lead couples the first and second connector elements of the first lead to the IMD.

16. Regarding claims 2 and 8, the system of Smyth is inherently capable of applying high-voltage therapy.

17. Regarding claims 3 and 9, it is inherent that when a second electrode is added on the first lead, as taught by Smyth (see col. 2, ln. 51-53), the first lead would require a third insulated conductor to couple the second electrode to the connector terminal of the implantable medical device. Furthermore, the second electrode added on to the first lead is inherently capable of applying low-voltage therapy.

18. Regarding claims 4 and 10, when a second electrode is coupled to the first lead, it is inherent that the second conductor of the first lead is capable of coupling the second electrode to the second connector element of the connector terminal of the first lead.

### ***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the



invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claims 1, 2, 4, 5, 7, 8, 10, 11, 16-20, 23, 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, previously cited, in view of Scheiner. Regarding claims 1, 2, 7, 8, 16, 19, 20, and 23, Levine discloses a system which includes a first lead 134, including first and second electrodes (see col. 5, ln. 60-67), auxiliary connector port 60 including first, second, and third connector elements (see Figure 9), a second lead 136, an insulated conductor, and a connector terminal. Furthermore, Levine discloses that the auxiliary port engages the connector terminal of the second lead and couples the second lead to the first lead, and further couples the first and second leads to the IMD (see Figure 9). However, Levine fails to disclose the use of an electrode adapted for high-voltage therapy included on the second lead 136, and directs the invention towards use with a pacemaker apparatus. Scheiner discloses a lead system that can be used with a pacemaker that includes a defibrillator coil (see

col. 15, ln. 1-2). The defibrillator coil of Scheiner is utilized in order to reverse life-threatening arrhythmias (see col. 1, ln. 41-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize a defibrillator coil, as taught by Scheiner, in conjunction with the pacemaker lead system of Levine in order to reverse life threatening arrhythmias and return the heart to normal rhythm.

22. Regarding claims 4 and 10, it is inherent that the second conductor of the first lead is capable of coupling the second electrode of the first lead to the second connector element of the connector terminal of the lead (see Figure 9).

23. Regarding claims 5 and 11, Levine discloses that the first lead includes a switch adapted to reversibly disconnect the coupling of the second conductor to the second electrode of the first lead (see col. 20, ln. 10-13).

24. Regarding claim 17, Levine discloses in Figure 9 a third connector contact which electrically engages a second high-voltage electrode of the second lead and the first conductor couples the first connector element to the third connector element.

25. Regarding claim 18, in order for the second low-voltage electrode of the second lead of Levine to be operable, the auxiliary port must inherently include a fourth connector contact adapted to couple the second low-voltage electrode.

26. Regarding claims 25 and 28, in Figure 9 Levine discloses a second connector contact 92 which couples a second electrode of the other medical electrical lead, including a third insulated conductor 94 for coupling the first connector element 68 to the second connector contact.

27. Regarding claims 26, 27, and 29, Levine discloses the invention essentially as claimed but fails to disclose third and fourth electrodes with third and fourth connector elements. Scheiner discloses in Figure 15A that the lead may include up to four electrodes, electrodes 453, 454, 461, and 462. Therefore, Scheiner discloses third and fourth electrodes which would inherently require fourth and fifth insulated conductors to couple the electrodes to the connector. Third and fourth electrodes are implemented by Scheiner in addition to the first and second electrodes on the first lead in order to provide for sensing and pacing in both the atria and ventricles and as part of a defibrillation therapy system (see col. 18, ln. 1-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to implement third and fourth electrodes, and their corresponding conductors, in the first lead of Levine in order to provide for sensing and pacing in both the atria and ventricles and as part of a defibrillation therapy system.

#### ***Allowable Subject Matter***

28. Claims 13 would be allowable if rewritten or amended to overcome the double patenting rejection set forth in this Office action.

29. Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-

1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto  
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TKH